

Remarks

Claims 1, 3-5, 8-13, 16, 17, 19, 20, 28-32, 34, 36 and 61-97 are presently pending in the subject application. Claims 2, 6, 7, 14, 15, 18, 21-25 and 27 have been canceled herein without prejudice to the prosecution of the subject matter of these claims in this or a future continuing application. Reconsideration and allowance in view of the above amendments and the following remarks are respectfully requested.

Claims 62-97 are newly added. New claim 62 recites a concentration range for the polycationic polymer in the sample that previously appeared in prior claim 6. New claim 63 is prior claim 27. New claims 64-67 relate to the nature and concentration of the dissociating reagent. Support for new claims 64-67 can be found in the specification at, for example, page 37, lines 25-26. New claim 68 and its dependents are similar to claim 1 and its dependents, with the exception that claim 68 specifies that the cationic monomers of the polymer are in molar excess of the phosphate groups of the probe, a limitation which appeared in prior claim 2. Additionally, new claim 68 does not include the polymer weight and concentration limitations of amended claim 1. These limitations separately appear in new claims 90 and 92, each of which depends from claim 68.

Objection to the Claims

Claim 16 is objected to by the Examiner under 37 C.F.R. § 1.75(c) for failing to further limit the subject matter of a previous claim. In support of this objection, the Examiner contends that claim 1 recites that the dissociating reagent is provided to the sample “in an amount sufficient to dissociate said polymer from said complex after said probe and said target nucleic acid have had sufficient time to associate in said sample” (emphasis added). Claim 1 actually specifies that the dissociating reagent is provided in an amount sufficient to dissociate the polymer from the duplex comprising the probe and the target nucleic acid. The complex of claim 16 refers to a complex comprising the recited polycationic polymer. As provided at page 6, lines 27-28, of the specification, the polycationic polymers of the claimed invention form complexes in a preferred embodiment. This is consistent with Applicant’s definition at page 18, lines 29-30, of the

specification, which provides that a “complex” is a composition comprising a plurality of polycationic polymers. Further, claim 16 has been amended herein to include the limitation of prior claim 2, reciting that the cationic monomers comprising the polycationic polymer are in molar excess of the phosphate groups of the probe. This additional limitation in claim 16 is consistent with one of Applicant’s theories regarding the mechanism by which the claimed method works, which is that the polycationic polymers are assembling in solution to form complexes that attract the polynucleotides. *See* specification at page 29, line 29 *et seq.* Thus, Applicant submits that claim 16 is further limiting of claim 1 and, accordingly, withdrawal of the Examiner’s objection to claim 16 is respectfully requested.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1-25, 27-32, 34, 36 and 61 stand rejected by the Examiner under 35 U.S.C. § 112, first paragraph, for failing to satisfy the written description requirement. In response, Applicant has followed the Examiner’s suggestion, in part, by amending claim 1 to include the limitations of canceled claims 6 and 7. However, Applicant has elected not to amend claim 1 by incorporating the limitation of canceled claim 2, since one of Applicant’s theories of operation is that polycationic polymers assemble in solution as they bind the polynucleotides. *See* specification at page 30, lines 5-8. As discussed above, the limitation of prior claim 2 now appears in amended claim 16, as well as in newly added independent claim 68. Thus, Applicant submits that the basis for the Examiner’s rejection has been overcome and, accordingly, withdrawal of the Examiner’s written description rejection is respectfully requested.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 17, 18 and 21 stand rejected by the Examiner under 35 U.S.C. § 112, second paragraph, as being indefinite. Claim 17 has been amended herein to clarify that the recited polymer is the polycationic polymer of claim 1 and claims 18 and 21 have been canceled herein. Accordingly, withdrawal of the Examiner’s indefiniteness rejection is respectfully requested.

Reply Under 37 C.F.R. § 1.111
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Conclusion

Applicant submits that the instant application is in condition for allowance and early notice to that effect is earnestly solicited.

Please charge the fees due in connection with this Reply to Deposit Account No. 07-0835 in the name of Gen-Probe Incorporated.

Respectfully submitted,

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